

**Notice of Allowability**

Application No.

10/667,161

Applicant(s)

PEYMAN, GHOLAM

Examiner

Humera N. Sheikh

Art Unit

1615

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 23 January 2006.
2. ☒ The allowed claim(s) is/are 10,11,13-22,24-32 and 34-36.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 1/23/06
- ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Interview Summary (PTO-413), Paper No./Mail Date 2/24/06
- ☒ Examiner's Amendment/Comment
- ☒ Examiner's Statement of Reasons for Allowance
- ☐ Other \_\_\_\_\_

*Humera N. Sheikh*  
HUMERA N. SHEIKH  
PATENT EXAMINER  
TC-1600

## **DETAILED ACTION**

### **Status of the Application**

Receipt of the Response to Non-Final Office Action, the Amendment, Applicant's Arguments/Remarks, all filed 10/05/05 and the Information Disclosure Statement (IDS) filed 01/23/06 is acknowledged.

Claims 10, 11, 13-22, 24-32 and 34-36 are pending in this application. Claims 10, 13, 22, 26 and 32 have been amended. Claims 1-9, 12, 23 and 33 have been cancelled. Claims 10, 11, 13-22, 24-32 and 34-36 are allowed.

### ***Information Disclosure Statement***

In the Information Disclosure Statement (IDS) filed 01/23/06, the two reference documents on pages 1 and 2 (AU 17386/88 & AU 20350/92) which have been crossed off by the Examiner, have been considered and made of record by the Examiner, however, the crossed off reference documents will not be printed on the face of the patent publication. The references are missing appropriate dates.

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Beverly A. Lyman on February 24, 2006.

The application has been amended as follows:

**In the Claims:**

In claim 10, line 5, between the words 'replacement' and 'further' a comma (,) has been added.

In claim 11, line 2, between the words 'one' and 'of', the phrase "**selected from the group consisting**" has been added.

In claim 19, line 2, between the words 'one' and 'of', the phrase "**selected from the group consisting**" has been added.

In claim 22, line 4, between the words 'from' and 'anti-cell proliferation', the words "**the group consisting of**" has been added.

In claim 25, line 2, between the words 'one' and 'of', the phrase "**selected from the group consisting**" has been added.

In claim 31, line 2, between the words 'one' and 'of', the phrase "**selected from the group consisting**" has been added.

In claim 36, line 2, between the words 'one' and 'of', the phrase "**selected from the group consisting**" has been added.

**In the Abstract:**

In the first line, the term 'Ocular Solutions' has been deleted.

***Allowable Subject Matter***

Claims 10, 11, 13-22, 24-32 and 34-36 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that the prior art (Ueno – U.S. Patent No. 6,872,383; Kaswan – U.S. Patent No. 5,411,952 & Tusé *et al.* - U.S. Patent No. 6,482,799 B1) does not disclose nor suggest or teach a therapeutic method as claimed that provides for a physiologic ophthalmic irrigating or volume replacement solution comprised of a macrolide antibiotic or mycophenolic acid in a concentration in the range between about 1 ng/ml to about 200 µg/ml, administered to the eye of a patient. The prior art further fails to disclose or teach or suggest a therapeutic method that provides for irrigating, wash or volume replacement, which also provides for an anti-inflammatory effect without increased ocular pressure. The prior art also fails to disclose or teach a therapeutic method comprising intraocularly administering to a patient undergoing cataract surgery, an ocular solution containing at least one of a macrolide antibiotic or mycophenolic acid at a concentration in the range from about 20 µg/ml to about 200 µg/ml, within a lens capsule prior to insertion of a replacement intraocular lens. Additionally, the prior art also fails to disclose or teach an article that comprises an implantable intraocular replacement lens in a solution containing a concentration of a macrolide antibiotic or mycophenolic acid ranging from about 20 µg/ml to about 2000 µg/ml, sufficient to provide the lens with at least one effect selected from anti-cell proliferation, anti-cell migration, anti-inflammatory, anti-angiogenesis, antimicrobial and antifungal. The prior art, either alone or in

combination, fails to disclose or teach the instant methods to irrigate or replace volume in an eye and fails to disclose or teach the specific articles containing agent at a defined concentration.

In contrast, the prior art teaches solutions (*i.e.*, eye drops) that must be dosed, which involves at least providing a concentration over a certain duration and is distinct from the instantly claimed method, which does not dose solutions, but rather uses the solutions at the volume and time necessary for irrigation, vitreous replacement or washing a surgical site.

The instant invention demonstrates an improvement over prior art formulations because it provides beneficial properties, such as reducing inflammation at a surgical site (anti-inflammatory effect), inhibits cell migration and cell proliferation (anti-proliferative and anti-migratory effects), inhibits the growth of new blood vessels at the site of an ocular tumor (anti-angiogenic effect) and reduces the growth of bacteria, fungi, etc. (anti-microbial and anti-fungal effects). Its anti-inflammatory effect desirably occurs without an increase in intraocular pressure, which may occur when steroids are administered to control ocular inflammation. Such a composition may be used in patients undergoing ocular surgery such as cataract surgery, retinal repair, etc. The macrolide and/or mycophenolic acid can also be added to a commercially available ocular solution, or can be formulated with an ocular solution.

Hence, in view of the improvements of the present invention and the lack of teachings of the instant limitations by the prior art, the instant invention is rendered non-obvious and patentable over the cited art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

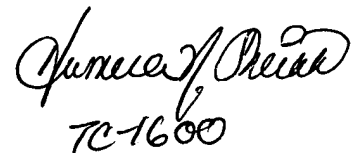
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Patent Examiner

Art Unit 1615

February 24, 2006



TC-1600